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# Fermilab Quality Assurance Plan

Diligent for Excellence



**Office of Quality and Best Practices**
**Fermi National Accelerator Laboratory**
**Batavia, IL**

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# TABLE OF CONTENTS

# OVERVIEW

# OVERVIEW

The U.S. Department of Energy's (DOE) Office of Science is the steward of a system of 10 world-class national laboratories. These laboratories perform basic research and research and development which is not well suited to university or private sector research because of its scope, infrastructure or multidisciplinary nature. These laboratories collaborate not only with each other for an effective synergy, but also with international teams of scientists and engineers. Five of these laboratories are multi-program facilities, while the other five are single-program facilities. The Fermi National Accelerator Laboratory (FNAL), also known as Fermilab, located in Batavia, Illinois, is one of the five single-program laboratories supported by the DOE.

The 6,800 acre Fermilab site was acquired in the late 1960's by the Atomic Energy Commission from the State of Illinois and was managed and operated by the Universities Research Association (URA) from that time until January, 2007. Since January, 2007 the Fermi Research Alliance, LLC (FRA), composed of URA and the University of Chicago, is the prime management and operating (M&O) contractor for the DOE at Fermilab. EG&G Technical Services, Inc. is an industry partner and subcontractor to FRA. Both organizations are committed to implementing plans, processes, and procedures that implement, institutionalize and continually improve the DOE Quality Management System (QMS) requirements at Fermilab.

Fermilab's QMS is required at the highest level by contract DE-AC02-07CH11359 between DOE and FRA. The contract identifies DOE Order 414.1C *Quality Assurance* as the requirements document for Fermilab's quality assurance program. The order requires contractors to ensure that the quality requirements are documented, effectively implemented, assessed and continually improved. The DOE Order 414.1C also requires that Fermilab flow down its quality assurance requirements to subcontractors at any tier to the extent necessary to ensure contractors' compliance with the requirements and the safe performance of work.

Implementation of Order 414.1C is documented at the first level within Fermilab's quality program via the Laboratory Director's Policy Manual, policy number 10 on Quality Assurance (QA Policy).

The Fermilab Quality Assurance Policy establishes the principles for the program and provides a link between the DOE order and the requirements established for the work conducted by Fermilab. The order and policy are implemented at the second level by this Quality Assurance Plan as required by the order, and at subsequent levels by implementing procedures necessary to ensure compliance and effectiveness.

This Quality Assurance Plan (QAP) describes the overarching institutional quality assurance program for Fermilab which is implemented using a graded approach to the application of controls based on the analysis of risk identified in areas where work is to be performed. It identifies the quality requirements necessary to implement DOE contract requirements throughout the Laboratory's divisions/sections in a consistent manner to ensure that quality and safety are integrated into all work conducted under the contract.

This QAP refers to Laboratory-wide manuals, policies and procedures that detail the activities which execute the Fermilab QA requirements. In many cases these activities are currently decentralized among the divisions/sections. Centralized implementations will leverage current activities and capture best practices. In cases where the documents do not exist, the full Laboratory-wide implementations will be developed according to a schedule based on availability of resources and perceived benefits.

In accordance with requirements of DOE O 414.1C Quality Assurance the QAP will be reviewed annually. If this review results in revisions to the QAP, OQBP will resubmit the QAP to DOE for review and approval and will identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements.

If the annual review of the Fermilab QAP does not result in any revision, OQBP will notify the DOE that the review was conducted and no revision is necessary.

## PURPOSE AND SCOPE

### PURPOSE

The purpose of the Fermilab Quality Assurance Plan is to implement DOE Order 414.1C in conjunction with Fermilab Director's Policy number 10 Quality Assurance while helping improve Fermilab's overall performance at meeting or exceeding customer expectations. This plan is designed to help sustain Fermilab's legacy and its abundant heritage of success and to demonstrate FRA's and EG&G's value as trusted, consistent and dependable partners with DOE.

The aim of the QAP is:

- to define a QA program which ensures that Fermilab's products and services meet or exceed customers' expectations.
- to provide the Laboratory with unambiguous requirements for the purpose of implementing and maintaining an integrated quality assurance program throughout the Laboratory,
- to provide a quality management system that is capable of monitoring, controlling and continually improving the program's activities, processes and systems,

### SCOPE

The QAP establishes the requirements necessary to comply with DOE Order 414.1C (under prime contract DE-AC02-07CH11359) and to implement the Fermilab Director's Policy number 10 on Quality Assurance in accordance with the aforementioned DOE order and contract. Compliance with the QAP is mandatory and applies to Fermi Research Alliance, LLC (including all legal entities under its exclusive control) and all its employees, contractors, subcontractors and Fermilab users when performing work that affects the Laboratory.

## PRINCIPLES OF THE QUALITY PROGRAM

- That quality is assured and maintained through a single, integrated, effective QA program. The quality program is implemented through a single Quality Assurance Plan. In an effort to limit duplication of effort and ensure both integration and consistent application throughout the Laboratory, there will be a single lab-wide implementing procedure (e.g. Corrective and Preventive Actions, Graded Approach) where that procedure can be extended beyond individual divisions and sections without detriment to its intention, compliance or effectiveness.

- That management support for planning, organization, resources, direction, and control is essential to QA. To this end, Fermilab's Director and the heads of each division and section will provide sufficient resources to the implementation of the QA program within the areas under their control to ensure effective compliance with requirements.

- That performance and quality improvement require thorough, rigorous assessment and corrective action. Reviews and assessments, including self assessments and management assessments within divisions/sections, and independent assessments / reviews (conducted by or for the OQBP, the Fermilab Assurance Council, the Laboratory Director, FRA or the DOE) are a welcome part of conducting business at Fermilab. This QA program is intended to augment the laboratories ability to conduct rigorous assessments and effective corrective actions by providing training and support to representatives of each division/section, and providing visibility to assessment planning, conduct and outcomes.

- That workers are responsible for achieving and maintaining quality. While the ultimate responsibility for ensuring an effective quality program lies with the Laboratory Director, the Director has delegated the responsibility for full and effective implementation of quality assurance to every Fermilab employee, user, and subcontractor in the conduct of work done at or for Fermilab and its customers. Responsibility for oversight of these individuals to ensure compliance lies with line management up to the heads of each Division/section. Responsibility for administration, maintenance and continued improvement of the quality program is delegated by the Laboratory Director to the Head of OQBP.

- That environment, safety, and health risks and impacts associated with work processes can be minimized. The quality program at Fermilab is implemented in conjunction with other relevant Fermilab programs including ES&H, to ensure that all work is conducted correctly, and in a safe and responsible manner.

- To establish quality process requirements to be implemented under a QA program (QAP) for the control of suspect/counterfeit items (S/CI), and the control of safety software. (The QAP extends beyond acting on customer issues, it includes proactively engaging in controlling incoming, in-process, and final materials, products, parts, etc.)

# CHAPTER 1

# PROGRAM

# 1. PROGRAM

## 1.1. INTRODUCTION

Fermilab's mission is defined as follows:

> *Fermi National Accelerator Laboratory advances the understanding of the fundamental nature of matter and energy by providing leadership and resources for qualified researchers to conduct basic research at the frontiers of high energy physics and related disciplines.*

Fermilab strives to meet this mission within the context of a safe and respectful workplace.

The format of the QAP and the quality program it documents is based on the following DOE O 414.1C ten criteria and a requirement to manage a suspect/counterfeit prevention program:

**Management**

Criterion 1 Program
Criterion 2 Personnel Training and Qualifications
Criterion 3 Quality Improvement
Criterion 4 Documents and Records

**Performance**

Criterion 5 Work Processes
Criterion 6 Design
Criterion 7 Procurement
Criterion 8 Inspection and Acceptance Testing

**Assessment**

Criterion 9 Management Assessment
Criterion 10 Independent Assessment

Supplemental Quality Management System Requirements for Suspect/Counterfeit Items (S/CI)

Each criterion and the S/CI requirement are addressed by separate chapters within this QAP with criteria 9 and 10 combined.

### 1.1.1. INTEGRATED SAFETY MANAGEMENT SYSTEM

Fermilab's integrated safety management system is documented in the Fermilab Environment, Safety and Health Manual (FESHM) in accordance with the requirements established in 10 CFR 851, *Worker Safety and Health Program*, the Integrated Safety Management System requirements prescribed in DOE Policy 450.4, DOE M 450.4-1 Integrated Safety Management Systems Manual and DOE Order 231.1A *Environmental, Safety and Health Reporting* This QAP is consistent with and complimentary to the Fermilab integrated safety management program requirements delineated in FESHM.

#### 1.1.2. CONTRACTOR ASSURANCE PROGRAM

Fermilab's contractor assurance program is documented in the [Fermilab Contractor Assurance Plan] in accordance with DOE Order 226.1A *Implementation of Department of Energy Oversight Policy*. This QAP is consistent with and complimentary to the Fermilab Contractor Assurance Plan.

## 1.2. RESPONSIBILITIES

### 1.2.1. ORGANIZATION

#### 1.2.1.1.DIRECTORATE

Fermilab's organization at the directorate level is depicted in Figure 1, the Fermilab directorate-level organization chart current at the time of this writing. The Fermilab Directorate is made up of the Laboratory Director, the Deputy Director, the Chief Operating Officer (COO), the Chief Financial Officer (CFO) the Director of Environment, Safety and Health ES&H, the Head of the Office of Quality and Best Practices (OQBP), the Associate Director (AD) of Accelerators, the ILC Program Director, and the Associate Director (AD) for Research. In addition there are two Assistant Directors and a number of support functions including the Fermilab Legal Office, the Office of Communications (formerly Public Affairs), the Office of Project Management Oversight (OPMO) and the Office of Research and Technology Applications (ORTA).

#### 1.2.1.2.DIVISIONS AND SECTIONS

Reporting to the Associate Director of Accelerators are the Accelerator Division (AD), the Technical Division (TD) and the Accelerator Physics Center (APC). Reporting to the Associate Director for Research are the Particle Physics Division (PPD), the Computing Division (CD), the Fermilab Center for Particle Astrophysics (FCPA, and the Compact Muon Detector (CMS) Center. Reporting to the Associate Director for Operations Support are the Facilities Engineering Services Section (FESS), the Business Services Section (BSS), and the Workforce Development and Resources Section (WDRS). Reporting to the CFO are the Accounting, Budget and MIS departments.

Within each Division, and Section is the necessary line management and support organizations to ensure their missions are achieved safely, and within budget. Divisions, Sections, Research Centers and the Directorate maintain organizational charts in their respective links, ( Divisions, Sections, Research Centers).

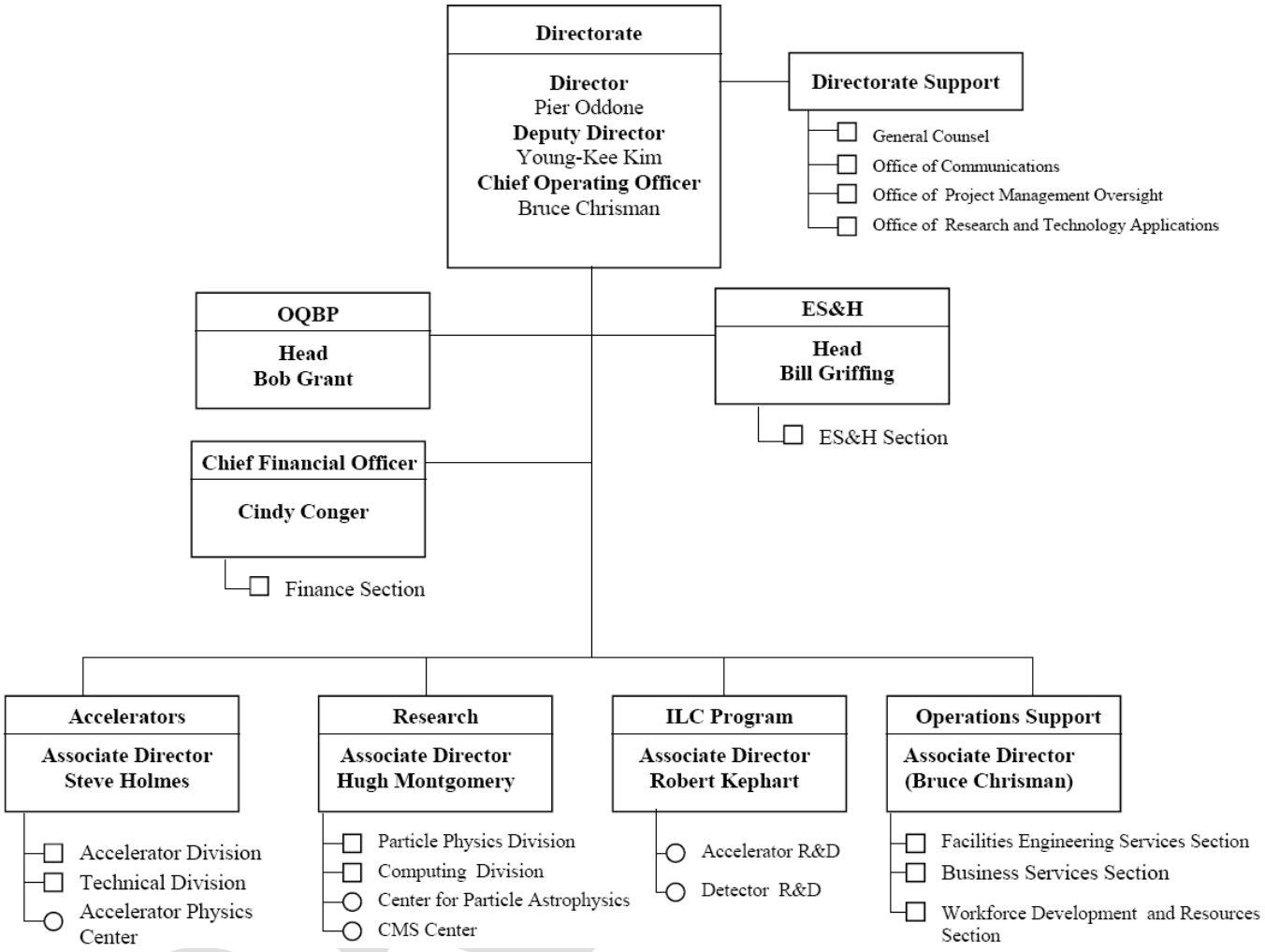


**Figure 1 Fermilab Directorate Organization Chart**

1.2.1.3.INTERNAL AUDIT

Fermi Research Alliance, LLC's (FRA) accounts, records and internal accounting policies and controls at the FRA Corporate Office and at Fermilab are subject to audit. Internal Audit is an independent office, which regularly provides reports to Fermilab Management, FRA and the Board of Directors Audit Committee. This results in a process to monitor the adequacy, effectiveness and performance of the internal controls and ensure prudent business practices and compliance with the Prime Contract between FRA and the Department of Energy.

1.2.1.4.ADVISORY COUNCILS

The Laboratory Director receives input, advice and recommendations from a number of advisory councils on matters relating to science and operations.

- Physics Advisory Committee (PAC)
  Composed of members from various external laboratories and universities, PAC considers proposals for current and future scientific and R&D programs in both particle physics and particle astrophysics, and advises the Director on strategic approaches to supporting such proposals. Typically serving four years, PAC participants are experienced and well respected in the high energy physics community.

- Accelerator Advisory Committee (ACC)
  Composed of members from various external laboratories and universities, AAC advises the Fermilab Director on accelerator upgrade plans and accelerator R&D, and associated strategic approach, aimed towards the development of future accelerator facilities. The AAC meets one-to-two times per year, typically in the spring and fall, for two and a half days at Fermilab.

- Advisory Council on Integrated Assurance
  An internal assurance council (AC) which reviews the overall management and operations (M&O), commitments, initiatives, and Laboratory improvement efforts, and advises the Laboratory Director regarding the level of compliance of these activities. The council pays special attention to the requirements denoted in DOE Order 226.1A.

- Diversity Council
  The Diversity Council is structured to foster organizational equity through programs carefully designed to increase the diversity of the Laboratory and to increase the participation of employees by organizing teams to develop the initiatives of the Council. The Council, a task force for change, will develop, implement, and maintain strategic programs with established goals for the Laboratory.

- Laboratory Collaboration Council
  Established by FRA, LLC and UChicago Argonne, LLC, the Laboratory Collaboration Council (LCC) is chaired on a rotating basis by the Laboratory Directors, of FNAL and ANL. The LCC explores ways in which both laboratories can promote efficiencies, best practices, synergies, and cost savings in support of research programs and creates working groups chartered by joint action of the Laboratory Directors. Working groups provide critical support for experiments at the Large Hadron Collider (LHC) operated at Europe's treaty-based particle physics laboratory (CERN), and for R&D and technology transfer as part of the ILC mission.

### 1.2.2. AUTHORITY AND RESPONSIBILITIES

#### 1.2.2.1.LABORATORY DIRECTOR

The director of Fermi National Accelerator Laboratory reports to the Chairman of the board of directors of Fermi Research Alliance, to the DOE Fermilab Site Office, and to the DOE Office of Science, and has ultimate responsibility and authority for quality at Fermilab. The director

approves the QA Policy and all substantive changes to it and is committed to and supportive of effective implementation of this QAP. The Laboratory Director appoints Associate Directors and other key scientific and management staff including the Head of the Office of Quality and Best Practices.

1.2.2.2.OFFICE OF QUALITY AND BEST PRACTICES

The Head of the Office of Quality and Best Practices, who reports to the Laboratory Director, is designated as the senior Fermilab official responsible for the development, implementation, assessment and improvement of the quality assurance program. The Head of OQBP approves the QAP and all substantive changes to it, advises and assists the Laboratory director in providing continuity, completeness, and appropriate standardization in the overall quality program, and is committed to and supportive of the quality programs. This responsibility includes policymaking, planning, reporting, oversight, and other activities required to achieve an integrated and effective QA program. OQBP ensures quality related training is provided. The Head of OQBP similarly advises the Directorate, divisions/sections on QA matters while line management within divisions/sections implement QA policy, this QAP and related procedures. OQBP is the point of contact for quality reviews.

The head of OQBP is the owner of the QAP and by policy administers and is the point of contact for the quality program. Revisions other than minor editorial changes must be reviewed by each Division, and Section and the OQBP, and comments adjudicated prior to issue of the approved revision to the document. Revisions which are other than minor, shall be denoted by a change in the integer portion of the revision number, and shall be approved by Laboratory Director upon review and recommendation of the head of OQBP. Minor editorial changes, those that do not add, diminish or otherwise change requirements must be approved by OQBP or an authorized designee. Minor changes shall be denoted by decimal values in the revision number and their approval shall be documented in the table of revisions only. The minimum review cycle for this manual is annually. New contractual requirements such as DOE Directives, affecting the quality program requires that the manual be reviewed to ensure that any requirement revisions are accommodated.

1.2.2.3.PROGRAMS, DIVISIONS, AND SECTIONS

Associate Laboratory Directors, and the heads of Programs, divisions/sections are responsible for quality in their respective organizations. As appropriate for their areas of responsibility and using the graded approach, they establish additional or more specific performance quality requirements than those established in the QAP while avoiding any unnecessary duplication of documentation or effort. They are responsible for the performance of assessments, and for sponsoring assessments, to facilitate the achievement of the organizational mission, objectives, and performance requirements. They are responsible for ensuring that their division's/section's activities are conducted in accordance with the principles and requirements of the QAP.

Each division/section appoints a Quality Assurance Representative (QAR), as a point of contact for implementation of the QA program.

1.2.2.4.STAFF RESPONSIBLE FOR ASSURANCE SYSTEMS

One of Fermilab's goals is to coordinate all assurance systems to the extent necessary and practicable. Certain members of the Assurance Council have key roles in this effort including.

- ES&H DIRECTOR

Reporting to the Laboratory Director, the ES&H Director is responsible for developing and maintaining assurance systems for the ES&H and emergency management programs and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- BUSINESS SERVICES SECTION HEAD

Reporting to the Associate Director for Operations Support the Head of Business Services is responsible for developing and maintaining the physical security assurance system and procurement assurance systems and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- COMPUTING DIVISION HEAD

Reporting to the Associate Director for Research, the Head of the Computing Division is responsible for developing and maintaining the cyber security assurance system and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- CHIEF FINANCIAL OFFICER

Reporting to the Laboratory Director, the CFO is responsible for developing and maintaining the financial assurance system and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- WORKFORCE DEVELOPMENT AND RESOURCES SECTION HEAD

Reporting to the Associate Director for Operations Support, the WDRS Head is responsible for developing and maintaining the human resource asset management assurance system and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- FACILITIES ENGINEERING SERVICES SECTION HEAD

Reporting to the Associate Director for Operations Support, the FESS Head is responsible for developing and maintaining the real property assurance system and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

- OFFICE OF PROJECT MANAGEMENT OVERSIGHT HEAD

Reporting to the Laboratory Director, the Head of Office of Project Management Oversight is responsible for developing and maintaining the program and project management assurance system and with the Head of OQBP for ensuring ongoing compatibility and integration with the QA Program.

1.2.2.5.ALL EMPLOYEES, CONTRACTORS, USERS, AND VISITORS

All Fermilab personnel including employees, contractors at any level, users and visitors are responsible for safety and the quality of their work and for being attentive to opportunities for continuous improvement. They are responsible for stopping any activity that poses imminent danger to any individual, the Fermilab or local mission, or the environment. Employees must inform their immediate supervisors of any conditions that are noncompliant with Fermilab policies and requirements.

## 1.3. GRADED APPROACH

### 1.3.1. GRADED APPROACH PROCESS PRINCIPLES

In accordance with DOE order 414.1C, the Fermilab quality program utilizes a graded, risk based approach to tailor the kinds and extent of controls applied to implement quality in fulfilling applicable requirements. The graded approach is implemented without compromising the safety of the public, employees or facilities, adversely impacting the environment, or failing to comply with DOE requirements, rules and regulations. The graded approach should be applied based on prudent management planning, cost, evaluation of risks related to each function, and the consequence of poor outcomes on the customer, the workers, the community, and the environment. Risk based ranking and subsequent adjustments based on other relevant factors supports the Laboratory' responsibility to allocate limited resources to areas where the activities have been identified as requiring the most control and oversight. [Graded Approach Procedure].

### 1.3.2. RESPONSIBILITIES

The OQBP is responsible for documenting the graded approach to be utilized by Fermilab and for providing training as necessary to ensure its continued implementation and effectiveness.

All division/section heads must ensure that a graded approach to quality requirements is used in accordance with this section for products, projects and services under their control.

All department heads and managers must use a graded approach when establishing the level of control for accomplishing quality program elements within their functional areas.

## 1.4. POLICY AND PROGRAM DOCUMENTS

Director's Policy # 10 Quality Assurance
Fermilab Environment, Safety and Health Manual (FESHM)
[Fermilab Contractor Assurance Plan]
[Graded Approach Procedure].

# CHAPTER 2

# PERSONNEL TRAINING & QUALIFICATION

# 2. PERSONNEL TRAINING AND QUALIFICATION

## 2.1. INTRODUCTION

All Fermilab employees, regardless of location, and personnel working on site at Fermilab must have the necessary experience, knowledge, skills, and abilities to perform their jobs. Personnel are qualified to perform their job based on one or more of the following:

- previous experience, education, and training;
- performance demonstrations or tests to verify previously acquired skills;
- completion of training courses or qualification programs;
- on-the-job training.

Initial employee qualification is ensured by the hiring process. This process is administered by the Workforce Development and Resources Section (WDRS), Individuals are hired to meet established position requirements as specified by job descriptions and skills as defined by line managers, Line managers ensure that job candidates meet specified requirements.

Training assists personnel in acquiring knowledge of the correct and current processes and methods to accomplish assigned tasks. It enables personnel to understand the fundamentals of the work, the associated hazards, the context within which the work is performed, and the reasons for any special work requirements. Types of training include:

- Institutional training - conveys general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

- Site-/facility-specific training - conveys the environmental, safety, emergency plans, security, and operational information necessary for personnel to prepare for and perform their assigned duties in the site/facility. This includes site-specific access requirements and regulatory based training. Management is responsible for defining training requirements and ensuring that the training is completed as required.

- Project-/task-specific training - imparts the knowledge required for personnel to perform their assigned duties safely and successfully. This training may include project/task goals and schedules, implementing procedures, safety and hazard controls, methods, requirements, process metrics, and skills. Project/task-specific training requirements should be defined by project managers and workers. This category includes experimental operations, accelerator and beamline operations, R&D and test facility operations.

Administrative controls must be placed on new employees prior to their completing certain training. Such controls, administered by the first-line supervisors, ensure

that employees do not work in areas or on tasks until they have received the minimum required level of training and can adequately and safely perform the assigned tasks without direct supervision.

The process for determining qualifications and developing and providing training is defined in [Managing Qualification and Training – to be written].

## 2.2. RESPONSIBILITIES

Fermilab line managers must ensure personnel possess the experience, knowledge, skills, and abilities that are necessary to fulfill their responsibilities. This is accomplished by using the graded approach to define the necessary training, and records of training, for each employee. This work includes:

- Developing an Individual Training Needs Assessment (ITNA) and revising it as job requirements change. The ITNA covers institutional and site-specific training.
- Identifying and providing required project/task-specific training. Project/task-specific training emphasizes correct performance of work, personal accountability and responsibility, and, where appropriate, provides an understanding of QA principles and the relevant management procedures.
- Maintaining appropriate records of training, as defined by the graded approach. The TRAIN database documents institutional and site-specific training. This database also contains training plans and history reports to assist line management and employees manage their training progress.
- Utilizing position descriptions, Hazard Analyses (HA), new employee requisitions, and/or the Medical Department's Work Activities Analysis Form (WAAF) to identify the functional requirements and any physical limitations. This ensures that a continuous match exists between the capabilities of the employee and the physical requirements and/or mental demands of the current assignment.

Each employee is responsible for:

- Participating with their supervisor in defining the necessary training
- Successfully completing all required training,
- Applying training on the job

Administrative controls must be used until personnel complete the training required for their assignments.

## 2.3. CONTINUING TRAINING

Personnel are provided continuing training as appropriate to ensure that job competency and compliance are maintained. Continuing training includes lessons learned, equipment

changes, procedure changes, and changes in technology. For all recurring training which is tracked by TRAIN, automatic notifications are sent to affected employees and their supervisors.

## 2.4. POLICY AND PROGRAM DOCUMENTS

Laboratory Director Policy number 19, (Training)
ES&H Manual section 4010, Training (ES&H Training)
WDRS Policy and Procedures Manual (WDRS Policy & Procedure Links)
ES&H Manual section 5310, Occupational Medicine (Occupational Medicine)
[Managing Qualification and Training]

# CHAPTER 3

# QUALITY IMPROVEMENT

# 3. QUALITY IMPROVEMENT

## 3.1. INTRODUCTION

Continuous quality improvement extends beyond the achievement of goals and performance indicators/measures and meeting customer expectations. The continuous improvement process at Fermilab is designed to foster a self-critical culture focused upon detecting, preventing and learning from conditions adverse to quality, such as accidents, incidents, deficiencies, and non-conformances. Improvement is accomplished through appropriate planning, design, implementation and assessment of activities.

Quality improvement demands awareness and constant examination of all activities, processes, systems, projects and programs. As such, individuals are responsible for the quality of all aspects of their job, especially in a constantly changing environment, and reporting issues. Therefore, the improvement process includes provisions for individual feedback and mechanisms to identify, analyze, and resolve quality issues, in order to prevent their occurrence or recurrence

Management encourages a no-fault attitude where individuals are empowered to identify opportunities for improvement and report problems so that deficiencies are identified and resolved. Even when individuals are reluctant to share concerns with their line management, Fermilab offers ways to elevate concerns and to communicate anonymously.

Fermilab maintains continuous quality improvement through a variety of activities, including training, design, assessments, observation by walk-through, inspections, tests, monitoring, reviews, and analysis. Issues and improvement opportunities are documented and managed utilizing corrective action tracking and lessons learned systems.

The lessons learned process is an integral part of continuous quality improvement through the sharing of relevant best practices throughout Fermilab and the DOE complex.

## 3.2. RESPONSIBILITIES

### 3.2.1. MANAGEMENT RESPONSIBILITIES

Senior laboratory management is responsible for:

- Ensuring quality objectives are established for relevant functions and levels within the organization using a graded approach. The quality objectives shall be verifiable and consistent with the quality policy.
- Creating systems which facilitate the quality improvement functions described below

Management at all levels is responsible for:

- Encouraging and enabling all individuals under their supervision to participate in the following quality improvement activities

- Identifying and analyzing opportunities for improvement
- Responding to discovery of quality related issues and following up on any required actions
- Documenting the failures and non-conformances that are identified from these efforts.

- For significant incidents, ensuring that problems are reported to the appropriate potentially affected management levels - program, facility, division/section manager, and/or Directorate - and that causes are identified and corrected. Fermilab will meet the requirements of DOE Order 231.1A, *Environment, Safety and Health Report*ing, and associated guides and manuals and FESM 3010.

The degree of these efforts should be commensurate with the degree of programmatic significance, financial impact, compliance, public relations, or environment, safety, and health risks associated with the problems.

The Office of Quality and Best Practices (OQBP) verifies that major program and project plans include quality plans. OQBP verifies that corrective actions escalated to the Directorate (per issues tracking procedure) have been implemented, are effective, and are examined for application within Fermilab and/or other organizations.

## 3.3. QUALITY IMPROVEMENT PROGRAM COMPONENTS

Quality improvement will be implemented throughout the organization using a structured, graded approach including the elements of planning, measuring, analyzing and improving. [Process Improvement Procedure].

### 3.3.1. PLANNING

Strategic planning for Fermilab is conducted by the Director. He is aided in this effort by external bodies such as the DOE High Energy Physics Advisory Panel and Laboratory Collaboration Council and internally by bodies such as the Fermilab Assurance Council and Directorate. The goal is to position Fermilab to be on the forefront of scientific discovery and to maximize the effectiveness of its physical and intellectual assets.

Input to the planning process includes feedback from management reviews, problem resolution, root cause analysis, lessons learned, and assessments

Planning for a specific year begins with DOE Field Work Proposals (FWPs) and the fiscal Performance Evaluation Measurement Plan (PEMP). As funding levels are set, the Fermilab director assigns priorities for the main programs at Fermilab.

Note – FWP's are high-level documents describing to Fermilab's main sponsors/customers within the Office of Science, and High Energy Physics (HEP) what research is planned for a coming year and what facilities will be used.

Fermilab's Fiscal Plan is in alignment with the Fermilab Strategic Plan. This shall be developed at the beginning of each financial year with DOE, and its aim is to develop agreeable targets for Fermilab to attain.
Each division/section will develop plans to support the needs of the Fermilab Strategic Plan. Plans shall include such things as responsibilities, schedules, resources required and defined processes to carry out intended work.

### 3.3.2. MANAGEMENT REVIEW

The Directorate shall review the adequacy, suitability and effectiveness of the Quality Management System, at least annually. [Management Review Procedure]

> Note – The "Management Review" can be a combination of reviews throughout the fiscal year.

Divisions/sections, Program and/or Project Managers will hold reviews based upon need. The frequency is adjusted to adequately manage all aspects of the activity, process, or system to satisfy the customer (internal or external), be proactive in problem prevention, and get the work accomplished.

Programs and Projects will be managed per DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets* and implemented by the requirements provide in [Project Management Procedure] from the Office of Project Management Oversight (OPMO).

### 3.3.3. QUALITY PROBLEM RESOLUTION ANALYSIS

The process of resolving quality problems includes:

- identifying a condition adverse to quality,
- evaluating its significance and extent,
- analyzing the problem and determining its causes,
- reporting the planned actions to the organization identifying the problem,
- assigning responsibility for correcting the problem,
- taking prompt containment action and documenting that action,
- examination of training processes, procedures, or management systems,
- determining corrective action and documenting that action,
- taking steps to prevent recurrence,
- replicating the actions where appropriate,
- verifying implementation,
- documenting closure, and
- determining effectiveness of the corrective and preventive actions for significant problems

### 3.3.4. ROOT CAUSE ASSESSMENT AND CORRECTIVE ACTION

Issues escalated to the Directorate through the OQBP and/or the Fermilab Assurance Council are subject to an initial review to determine if the issue is relevant to the Fermilab issue tracking system or if the issue should be managed through other Fermilab channels. Where deemed necessary, or appropriate, the AC and / or OQBP, may raise the issues to the Director of Fermilab and/or DOE.

Quality problems are analyzed individually and collectively to identify systemic quality problems, trends and opportunities for process improvement.

## 3.4. POLICY AND PROGRAM DOCUMENTS

Significant and Reportable Occurrences (FESHM 3010)
Issues Tracking Procedure (LINK tbd)
[Process Improvement Procedure]
Environment Safety and Health systems (ES&H)
[Project Management Procedure]
[Management Review Procedure]

# CHAPTER 4

# DOCUMENTS & RECORDS

# 4. DOCUMENTS AND RECORDS

## 4.1. INTRODUCTION

Fermilab documents that specify policies, prescribe processes, and/or establish design specifications and requirements must be controlled to ensure that the direction they provide is accurate, current, and approved by authorized individuals. Fermilab's system for managing Laboratory-wide policies and procedures is described in the [Document Control Procedure]. Additional document control requirements may be imposed by outside customers/sponsors, or be required for certain specific activities.

Fermilab records are managed in accordance with the Fermilab Records Management Policies and Procedures (Records Procedures).

## 4.2. RESPONSIBILITIES

Responsibility for lab wide policies and procedures is shared between the Directorate and the originating divisions/sections as assigned by the Directorate. Divisions/sections must establish methods to control procedural requirements, design, and other quality management documents and records used solely within their division. Management is responsible for providing the resources necessary to fulfill the document control and records management requirements.

Fermilab employees, users, and contractors must comply with the document control and records management policies and procedures in place at Fermilab.

## 4.3. DOCUMENTS

Documents are required to safely and effectively manage, perform, and assess work. Using the graded approach, management shall identify those documents needed to accomplish these objectives and determine the level of control required. Controls include activities such as preparation, review, approval, distribution, usage, availability, revision and disposal of documents.

In accordance with the Fermilab Directors Policy number 13, *Document Control*, (Document Control) all policies, program documents, program implementation plans, and procedures shall be controlled by the issuing organization and the issuing organization shall schedule reviews and updates for each document under its control as prescribed by that document.

Fermilab will establish a Laboratory-wide document control system. Division/sections may establish systems to control procedural requirements, design, and other quality management documents used solely internally.

## 4.4. RECORDS MANAGEMENT

Records are necessary to provide evidence of conformity with requirements and of process effectiveness. Fermilab policies and procedures for records management are maintained by

Records Management and described in more detail in the Records Management Policy and Procedures (Records Procedures). The system includes provisions for specifying, preparing, reviewing, approving, disposing, and maintaining records and references applicable rules, regulations and directives governing how the Laboratory is to manage records. Fermilab will establish a centralized records management system.

### 4.5. POLICY AND PROGRAM DOCUMENTS

Directors Policy 13, *Document Control*, (Document Control)
[Documents Control Procedures]
Records Management Policies and Procedures (Records Procedures)

# CHAPTER 5

# WORK PROCESSES

# 5. WORK PROCESSES

## 5.1. INTRODUCTION

Work includes the design, operation, maintenance, modification, and construction of structures, systems, components, or experiments by Fermilab employees, regardless of location, and personnel working on site at Fermilab. A graded approach is used to determine the level of controls applied to work performed at Fermilab.

The set of controls applied to work processes includes:

- written procedures for activities of sufficient complexity or potential hazard;
- periodically monitoring and assessing performance,
- personnel are responsible for their performance.
- specific provisions for activities not otherwise covered in this document, including facilities management, maintenance, materials management and shipping & receiving

As described in Section 3.3.1, Planning, Fermilab works to mutually agreed upon goals from the DOE and other stakeholders. Progress toward goals is monitored.

Clear lines of responsibility have been established for normal and emergency conditions.

Research work is performed in accordance with generally accepted scientific methods.

All work is performed in compliance with applicable DOE and/or legal requirements.

## 5.2. RESPONSIBILITIES

### 5.2.1. MANAGEMENT

Management is responsible for ensuring sufficient resources are available and given to facilities, plant and equipment, processes, personnel, health and safety needs, and support services to maintain the site in an operational state.

Line management is required to evaluate and ensure that people performing work have the appropriate skills, background, and academic qualification or professional certification, and area or task specific training necessary to carry out the work per Section 2.2, Personnel Training and Qualification. Management is responsible for ensuring work controls are in place and effective.

### 5.2.2. ALL PERSONNEL

Each person is responsible for the quality of their work, reporting issues, and contributing to the integration of environment, safety, and health and productivity goals. All personnel are responsible for maintaining items to prevent damage, loss or deterioration and ensuring proper use. Personnel should make every attempt do their work correctly the first time, in accordance with established procedures and work instructions.

### 5.2.3. FUNCTIONAL RESPONSIBILITIES

5.2.3.1.FACILITIES MANAGEMENT

Management of the facilities and equipment is distributed between Fermilab Facilities Engineering Services Section (FESS) and the division/section in charge (landlord) of each facility. In general, FESS is responsible for the Laboratory's utility infrastructure, roads and grounds, and Wilson Hall. Divisions/sections are responsible for management of systems unique to their facilities to carry out specific functions. Subtleties within this general framework are negotiated and agreed upon between FESS and divisions/sections. The Condition Assessment Program and all Real Property reporting including administration of the DOE facility information management system (FIMS) is centrally managed by FESS for the laboratory. Director's policies 5, 18 and 36 provide additional detail on facility management responsibilities.

5.2.3.2.INVENTORY CONTROL

Management of inventory control is distributed among Business Services Section (BSS) and the division /sections. The BSS Inventory Control functions are described in the Property/Inventory Control Policy and Procedures Manual and include provisions for audits, turnover ratio, stock rotation and just-in-time procurements of common use items.

Division/sections are responsible for special process spares, normal spares, and other specialized inventories.

5.2.3.3.SHIPPING AND RECEIVING

The BSS shipping function ensures proper labeling, packaging and tracking of outgoing materials. The BSS receiving function is responsible for ensuring that products are properly received, accounted for, delivered on-site and dispatched. Some direct shipments are received by division/section facilities.

## 5.3. WORK PROCESS CONTROL

Work at Fermilab covers a wide range of complexity. Processes can range from very straightforward and prescriptive to very dynamic and non-prescriptive. Line management is responsible for applying the graded approach to determine the appropriate level of work process controls, which activities require written procedures, and which procedures can be augmented through the appropriate personnel training and qualifications. Management defines workmanship standards, equipment to be used, specification for materials, process measurement points and measurement standards.

Emphasis in defining work process controls is placed upon prevention. Details of in-process and post-process quality checks could be included in procedures. Records of quality checks are used as the basis of feedback for process quality improvement.

ES&H requirements and controls for work processes are defined in FESHM.

## 5.4. SPECIFIC PROVISIONS FOR PROCESSES NOT ALREADY DESCRIBED

Controls are established for the procurement and acceptance of items and services and are addressed in Section 7, Procurement.

Measuring and Test Equipment Control are designed to meet requirements identified in Chapter 8.

### 5.4.1. ITEM CONTROL

Using a graded approach, items are identified, controlled, with their traceability maintained during receipt, shipping, storage, handling, installation, use and disposal. These controls are commensurate with the item's application, usage and associated risk, and defined in [Material Control].

The requirements for controlling and maintaining property, equipment, items, and the site infrastructure follow DOE Order 430.1B, *Real Property Asset Management*. Personal property is controlled according to [ Property/Inventory Control Policy & Procedure Manual].

Chapter 10 describes the control of Suspect/Counterfeit Items.

### 5.4.2. PREVENTIVE AND PREDICTIVE MAINTENANCE

Divisions/sections are responsible for maintaining equipment to prevent damage loss or deterioration. Scheduling and maintenance requirements are documented within each division/section maintenance plans. Records of maintenance are kept.

Facilities, tools and equipment are evaluated for critical replacement or consumable parts. Appropriate planning is completed to ensure these parts are available to minimize downtime.

### 5.4.3. READINESS REVIEWS

Readiness reviews are conducted prior to the start of operations that are new or have been significantly changed. The extent and detail of the reviews are commensurate with the scale, cost, complexity, hazards, and programmatic significance.

### 5.4.4. CALIBRATION OF PROCESS EQUIPMENT

It is the responsibility of each division/section to identify, monitor and maintain key process equipment that requires calibration or verification. Results shall be maintained. (See also chapter 8.)

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### 5.4.5. WORK ENVIRONMENT

All facilities shall be maintained in a state of order, cleanliness and repair, appropriate for accomplishing its mission. It is everyone’s responsibility to maintain the integrity and cleanliness of their work area, assure they understand and meet the requirements at each building location, and follow the general expectation for Fermilab.

### 5.4.6. TRANSFERING THE RESULTS OF RESEARCH

Fermilab does not engage in significant technology transfer and essentially all of its work is published in open literature. The main scientific output, technical papers, are published in peer reviewed journals. The Fermilab Office of Research and Technology Applications (ORTA) manages technology transfer and as appropriate in coordination with the Laboratory Collaboration Council (LCC) utilizes ANL Technology Transfer resources.

## 5.5. SAFETY SOFTWARE

Fermilab does not employ safety software under the definition of safety software in DOE Order 414.1C Quality Assurance. The governing policy, available on the Computing Division web site states:

> *It is Fermilab policy to avoid reliance on a computer as an essential element of any system that is necessary to protect people from serious harm, to protect the environment from significant impact, or to protect property the loss of which would have a serious impact on our mission. The use of computers for monitoring, data logging, and reporting is encouraged, however computers used for these purposes must not be essential for protection. Contact the Fermilab Computer Security Executive for any variance.*

## 5.6. POLICY AND PROGRAM DOCUMENTS

Fermilab Environment Safety & Health Manual FESHM
[Material Control].
[ Property/Inventory Control Policy & Procedure Manual].

# CHAPTER 6

# DESIGN

# 6. DESIGN

## 6.1. INTRODUCTION

Fermilab shall establish a design process that provides appropriate control of planning, design inputs, outputs, verification and validation, configuration and design changes, and technical and administrative interfaces. Design work shall be based on sound engineering judgment, scientific principles, and applicable codes and standards.

The controls and implementing procedures shall be contained in the [Fermilab Engineering Manual] and its implementing procedures [FEMP].

The FEMP shall define a graded approach to engineering controls and configuration management that couples the applicable rigor of management controls to the risk posed by the structures, systems, and components, software for engineering design, or construction and manufacturing processes under development (hereafter referred to as design elements).

## 6.2. RESPONSIBILITIES

### 6.2.1. FERMILAB CHIEF ENGINEER

The FEMP is managed by the Fermilab Office of the Chief Engineer.

### 6.2.2. DIVISION/SECTION/PROGRAM MANAGEMENT

Management shall authorize resources, provide resources, assign engineering oversight and ensure functional requirements are established. For projects of sufficient complexity, size or risk, a Design Authority (DA) shall be designated.

### 6.2.3. DESIGN AUTHORITY

The DA is responsible to ensure the assigned design effort follows the prescribed Fermilab processes. DAs can be:

- A management authority responsible for existing design elements
- A scientific team leader for research facilities, equipment, apparatus, software, or processes
- The project engineer or other appointed individual as designated by the manager of a program/project.

DAs are expected to consult with subject matter experts, safety committees, and operations management; but are ultimately responsible for the final design and configuration of design elements.
Specifically, DAs are responsible for:

- Understanding functional requirements and developing specifications and technical requirements
- Design control and technical adequacy of the design process

- Specifying quality requirements for the acquisition of components and services
- Managing the change review process for the functional requirements and specifications
- Providing a formal notification to the client (user/customer) for changes that affect scope
- Closing-out design documentation

## 6.3. DESIGN PROCESS STEPS

The following controls are applied as appropriate using a graded approach.

### 6.3.1. PLANNING

The requirements including acceptance criteria are understood by all the relevant divisions, sections and departments. These requirements shall be documented and updated accordingly.

All parties agree on the organizational and technical interfaces by arranging information and communication channels.

After sufficient design iteration, requirements, plans, cost and schedule estimates are established as the baseline. From this stage forward changes are managed in accordance with the project's configuration management plan and implementing procedures.

### 6.3.2. INPUTS

Design inputs and constraints, including applicable orders, codes, standards, policies, and procedures, etc., will be identified. Design inputs are reviewed for accuracy and completeness and to identify any ambiguity or conflict.

### 6.3.3. PROCESS

The design process translates inputs into design output documents and actions that are technically correct and compliant with requirements.

The design process is managed by the DA. The design process controls are applicable to in-house, contracted, and collaborative design activities and services. Those providing contracted design services are evaluated and selected based on their ability to meet specified requirements demonstrated by equivalency of their programs or adherence to Fermilab processes. Collaborative design activities are generally governed by Memoranda of Understanding (MOU) and Statements of Work (SOW).

Design processes apply to original design and design changes / modifications.

Design efforts undergo risk evaluation by the DA to define the level of steps / level of rigor of controls prior to commencement of work.

When applied to research and development activities, design processes are tailored to meet the controls necessary for successful outcomes. As appropriate, R&D / experimental plans must specify the necessary controls and documentation contained in the activity's / project's Project Execution Plan (PEP) and be approved by the DA.

6.3.4. OUTPUTS

The completed design is recorded in design output documents such as drawings, specifications, test/inspection plans, fabrication/assembly procedures, maintenance requirements, and reports. As-built drawings and fabrication/assembly procedures are maintained after production or construction to show actual configuration.

A documentation package including qualification test results, final revisions of fabrication drawings, marked as-built drawings, proof-tests, operational readiness review/readiness assessments, etc., is assembled and retained as the final design closeout package.

6.3.5. REVIEW

Reviews are conducted at a level commensurate to the scope and complexity of the design to ensure conformance to requirements. As appropriate, design reviews may be formal, structured, documented, and are comprehensive and objective.

Design reviews are performed by technically knowledgeable persons and may include technical experts from outside the design team and in certain cases, outside of the Laboratory.

6.3.5.1. VERIFICATION

Fermilab has a documented verification process that reviews design outputs against their ability to meet requirements.

6.3.5.2. VALIDATION

Design validation is accomplished through the use of the construction/assembly or by testing the complete prototype system (or subsystem) during and after assembly. Results of validation tests are documented and maintained.

6.3.6. CHANGES

A design change is defined as one that alters a component or system function, method of performing the function, or design configuration.

Levels of change control vary with the magnitude of the proposed change. Proposed changes are reviewed by the same organizations that reviewed and approved the original design. This ensures that changes do not inadvertently challenge or violate safety or operational boundaries or conditions set by the original design.

Temporary modifications receive the same levels of control as permanent modifications.

Clients shall inform the DA of any new requirements/changes to specifications or acceptance methods via established communication channels. The DA reviews changes to the functional requirements and specifications against their ability to meet requirements.

Changes to requirements are documented and all relevant divisions/sections and departments are made aware of the changes involved.

6.3.6.1. CONFIGURATION MANAGEMENT

Items under configuration control include plans, specifications, analyses, and design basis. They provide an accessible, archived history of initial baseline, modifications and changes.

Changes, additions, and modifications to the design processes are controlled in accordance with the activity's / project's configuration management plan and implementing procedures.

Closeout documentation is inspected, reviewed, and accepted by the DA.

## 6.4. POLICY AND PROGRAM DOCUMENTS

[Fermilab Engineering Manual]

Fermilab Engineering Manual Procedures [FEMP].

# CHAPTER 7

# PROCUREMENT

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# 7. PROCUREMENT

## 7.1. INTRODUCTION

This section establishes the QA requirements for the Fermilab procurement process. The process expectations are as follows:

- items and services provided by suppliers meet or exceed the requirements and expectations of the designer and end user;
- requirements are accurately, completely, and clearly communicated; and
- the proper product or service is delivered on time.

Fermilab management controls exist for procurements through the FRA prime contract and Procurement Policies, and Procurement Manual.
All purchased materials and services shall be acquired by purchase order or procurement credit card (Pro-card).

All controls discussed below are applied using a graded approach.

All materials and services are purchased from technically acceptable and responsible suppliers and approved per procedures in the Procurement Manual.

Suppliers shall comply with all specifications and terms and conditions, as incorporated into the purchase order.

Fermilab suppliers shall provide goods and services which are in conformity with purchase order requirements Fermilab may, in accordance with purchase order terms and conditions, perform site audits, require suppliers perform self-assessments, control plans and/or data or other reports to insure compliance.

> Note - Changes to purchase order requirements may be made only by written agreement of the parties.

The procurement and receipt inspection processes support the identification and prevention of the introduction of suspect and counterfeit items (S/CI). The system for S/CI detection prior to release for use is detailed in Chapter 10 Suspect and Counterfeit Items.

## 7.2. RESPONSIBILITIES

The procurement of all goods and services is under the control of the Business Services Section (BSS), except where delegated by the Head of the Business Services Section.

### 7.2.1. BSS PROCUREMENT DEPARTMENT

The Procurement Department is responsible for the coordination of all procurement issues. This responsibility includes acquisition planning in association with engineering, quality and other functions as necessary, generating and verifying solicitation and purchase documents, and negotiating terms and conditions and performing subcontract administration.

All procurements using Pro-cards are restricted to dollar value maximums and item or service type as described in the Procurement Manual. The Procurement Department reviews all Pro-card purchases to ensure such purchase transactions are properly authorized and that any abuse is detected. All unauthorized use of the Pro-card system is escalated to the appropriate management authority.

#### 7.2.2. REQUESTOR

The requestor is responsible for providing complete specifications, statements of work, drawings, and/or other pertinent technical data, in support of the purchase requisition to Procurement. Documentation that pertains to purchase order requirements, such as certifications and supplier's data, source inspection, vendor qualification or certification, lot traceability, material safety data sheet (MSDS) requirement, industry standards, and acceptance sampling is included in the purchase requisition if required.

The requestor is responsible for verifying that all documentation and product is received per purchase order. The requestor is also responsible for assuring incoming technical inspections or tests are performed and/or vendor supplied data is analyzed for purchase order requirements prior to final acceptance.

#### 7.2.3. SHIPPING AND RECEIVING

Shipping and Receiving responsibilities are described in Chapter 5.

### 7.3. PROCUREMENT DOCUMENTS

Fermilab procurement documents are generated and managed in accordance with the Procurement Manual. These documents must include specifications, standards, and other applicable documents referenced in the purchase requisition and shall be incorporated into the purchase order.

### 7.4. SUPPLIER EVALUATION

Prospective suppliers are evaluated based upon their ability to meet quality, technical and financial performance criteria, and to operate in a safe and environmentally compliant manner. The Graded Approach is used to determine the level of evaluation and controls. Potential suppliers should be identified early in the design and procurement process to allow sufficient time to evaluate their capabilities. The supplier evaluation process is the joint responsibility of Procurement and the requester when technical expertise is necessary.

Evaluation and monitoring of supplier's performance during the life cycle of the purchase order are performed to ensure that technically acceptable items are produced and services continue to meet the quality, technical, delivery, and other performance requirements. Corrective actions are implemented should suppliers not perform as required.

Flow down of requirements to subcontractors at any tier is assured through terms and conditions of the purchase order.

The supplier evaluation and monitoring process is addressed in the Procurement Manual.

### 7.5. PURCHASE REQUISITION REVIEW

The purchase requisition is created, owned, and processed by the requestor and division or area requisition preparer. Responsibility for the accuracy of purchase requisition data and requirements resides with the requestor. Requisitions are reviewed and approved by the requisitioning organization prior to being processed by BSS Procurement.

Controls are applied based on purchase categories, dollar value and ES&H impact.

Procurement may return incorrect or incomplete purchase requisitions. A history of issues and revision is maintained within the financial system.

### 7.6. POLICY AND PROGRAM DOCUMENTS

Procurement Policies and Procedures Manual (Procurement Documents)
ES&H and National Environmental Policy Act (NEPA) Procurement Review (FESHM 5010)

# CHAPTER 8

# INSPECTION AND ACCEPTANCE TESTING

# 8. INSPECTION AND ACCEPTANCE TESTING

## 8.1. INTRODUCTION

This section establishes the process for inspections and tests performed at Fermilab to verify that physical and functional aspects of items, services, and processes meet requirements and are fit for use. The performance expectations, inspections, and tests are considered during the design phase and, where appropriate, specified in the design output and/or procurement documents. The graded approach is used to determine the level of controls applied to specific activities.

## 8.2. RESPONSIBILITIES

Line management is responsible to specify when and what type of inspections are required. Additionally, line management is responsible to ensure that adequate inspections are performed.

## 8.3. INSPECTION AND TESTING PROCESS

Inspection and acceptance testing plans, where applicable, identify item characteristics and processes to be inspected/acceptance tested, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing the inspection. Where deficiencies are identified appropriate corrective and/or preventative actions are taken. [Corrective Action, Preventive Action].

When appropriate, inspections and tests are performed by personnel who are independent of the activities being inspected.

### 8.3.1. CONTROL OF NONCONFORMING ITEMS

Items which do not conform to specified requirements are controlled to prevent their inadvertent installation or use. Controls include identification, documentation, evaluation, segregation (when practical), item disposition (reject, repair, rework, use-as-is) and notification of affected organizations.

FESHM manual 3010 (SIGNIFICANT AND REPORTABLE OCCURRENCES) should be consulted to determine if the nonconformance is reportable.

### 8.3.2. CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and test equipment (M&TE) used for inspection and acceptance tests are identified, calibrated, maintained, and controlled commensurate with their intended use. Procedures are established for testing, retesting, adjusting, and recalibrating M&TE.

Equipment is checked to ensure that it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records.

The process of calibration compares an unknown or test item or instrument with reference standards according to a specific procedure. Calibration standards are traceable to the National

Institute of Standards and Technology (NIST) or equivalent. Where no recognized standard exists, the basis for calibration must be defined and documented.

When M&TE or standards are found to be out of tolerance, appropriate evaluations are performed to assess any adverse impact on previous inspection, testing, data collected or calibration using that equipment and to determine the acceptability of items previously inspected or tested and appropriate notifications made. The evaluation, including conclusions, is documented.

All M&TE equipment not operating to specifications is identified and pulled from service or locked out. Equipment in this state is not returned to service until passing calibration requirements.

Consideration is given to computer programs that are part of the calibration of the equipment when calibrating and/or checking the equipment for use.

### 8.4. INSPECTION AND TEST RECORDS

Inspection and test results are documented and preserved.

The inspection and/or test status of items and processes requiring examination are clearly identified to ensure that only those with acceptable inspection and test results are used.

### 8.5. POLICY AND PROGRAM DOCUMENTS

FESHM 3010 (SIGNIFICANT AND REPORTABLE OCCURRENCES)
[Corrective Action Preventive Action]

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# CHAPTER 9

# ASSESSMENTS

# 9. ASSESSMENTS

## 9.1. INTRODUCTION

This chapter describes the program used to assess the adequacy, implementation and effectiveness of Fermilab processes and systems. This program includes both internal assessments used as part of the Laboratory management process (both management and independent assessments), and externally imposed audits and reviews (independent assessments).

Internal assessment is used by an organization to evaluate its own management processes and their implementation in an effort to identify good and noteworthy practices, uncover issues, identify corrective actions, and ensure that the work being performed is satisfactory and in accordance with Fermilab requirements, the regulatory environment, and the mission. This includes both management assessments where an organization is assessed by its own personnel, and independent assessments using peers or other organization's personnel. Internal Fermilab assessments are conducted in accordance with the [Fermilab Assessments Manual].

External assessment may be an audit, surveillance, incident-based review or inspection conducted by individuals who are not Laboratory employees. These are all independent assessments.

## 9.2. RESPONSIBILITIES

The Fermilab quality program requires that managers assess their processes and identify and correct problems that hinder the organization from achieving its objectives. These assessments include personnel assessing their own work processes and independent assessments using other Laboratory or external personnel. Personnel performing independent assessments are appropriately qualified and have sufficient authority and freedom from line management to allow for an unbiased assessment.

Each division/section implements an assessment process in accordance with [ Fermilab Assessments Manual]. The heads of divisions/sections and ES&H and QA representatives monitor the progress of actions in their organizations on a periodic basis and ensure that the actions are finalized with appropriate objective evidence.

OQBP monitors the adequacy of the assessments and the progress of corrective actions.

The coordination of external assessments is performed by the OQBP.

## 9.3. ASSESSMENT RESULTS

Issues and opportunities for improvement identified as the result of an assessment are presented to the organization that was assessed, provided to the appropriate levels of management for review, and evaluated to determine the level of follow-up required.

Findings require a corrective action plan, disposition, follow-up, and verification and validation. The degree of validation shall be commensurate with the identified risks. Corrective actions

must be recorded and tracked to closure in accordance with the [Corrective Action Preventive Action].

Results from assessments are evaluated for reportability.

OQBP ensures that issues with Laboratory-wide implications are identified and corrective actions are implemented.

## 9.4. PROVISIONS FOR DOE AND OTHER EXTERNAL ASSESSMENTS

Fermilab provides accommodations (i.e., access, administrative support, facility space) for DOE and other external assessment teams.

Findings and corrective actions for DOE assessments are administered in accordance with the Contractor Requirements Document (CRD) of DOE O 470.2B, *Independent Oversight and Performance Assurance Program*. Findings and corrective actions for other external assessment teams (i.e., IEPA, sponsor audits) are discussed and agreed upon among the external assessment team, OQBP and the assessed organization.

## 9.5. POLICY AND PROGRAM DOCUMENTS

[Corrective Action Preventive Action]
[ Fermilab Assessments Manual]

# CHAPTER 10
# SUSPECT/COUNTERFEIT ITEMS

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# 10. SUSPECT AND COUNTERFEIT ITEMS

## 10.1. INTRODUCTION

In accordance with DOE O 414.1C and DOE G 414.1-3, Fermilab has established a process for the identification, control, and disposition of suspect/counterfeit items (S/CI). Implementation of the S/CI program can be found in [Suspect/Counterfeit Items Procedure]. Fermilab provides training on S/CI processes and controls (including prevention, detection and disposition of S/CIs).

## 10.2. RESPONSIBILITIES

Senior management is responsible for ensuring that S/CI training is available.

Line management is responsible for identifying individuals requiring S/CI training, ensuring they receive this training and providing necessary resources for implementing the S/CI program.

Designers should provide appropriate specifications and controls to safeguard the Laboratory against the introduction of S/CI.

Procurement is responsible for selecting technically acceptable and responsible suppliers including distributors authorized by the manufacturer.

All requestors and ProCard holders must be aware of the need to purchase from reputable suppliers and distributors.

All personnel are aware of the risks associated with S/CI and the S/CI reporting process.

## 10.3. PREVENTION

Methods to prevent the purchase of S/CI's are based on making all purchases from reputable suppliers and distributors.

## 10.4. DETECTION

The primary means of detecting S/CI's is through inspection.

## 10.5. REPORTING

If a S/CI is discovered the reporting process implements the requirements of the Suspect/Counterfeit Procedure] which includes notifying the area supervisor, Senior Safety Officer and Quality Assurance Representative.

FESHM manual 3010 (SIGNIFICANT AND REPORTABLE OCCURRENCES) should be consulted to determine the appropriate reportability category.

## 10.6. CONTROL OF NONCONFORMING ITEMS

This is described in Chapter 8 Inspection and Acceptance Testing.

10.7. POLICY AND PROGRAM DOCUMENTS

FESHM 3010 (SIGNIFICANT AND REPORTABLE OCCURRENCES)

[Suspect/Counterfeit Items Procedure].

1 TABLE OF REVISIONS

| Author(s) | Description | Revision | Date |
|---|---|---|---|
| QDT | Draft A11 – last QDT meeting of 2007 | 000 | 12/19/07 |
| Jed Heyes | Draft A12-1 Clean up per action items from QDT for submittal to OQBP including updated org chart, corrected TOC errors and date on cover page | 000 | 12/21/07 |
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